

REMARKS/ARGUMENTS

The claims in the application as now amended are 7, 8, 10 and 16-18. Claims 1-6, 9 and 11-15 now stand as canceled.

New Claim 16 is Claim 13 rewritten in independent form. All other claims depend directly or indirectly from Claim 16.

New Claim 17 recites compounds (5), (6), (34), (35), (41) to (46) and (54) to (63) of Claim 5 and depends from claim 16.

New Claim 18 recites the compounds recited in Claim 6 other than the second compound and also depends from claim 16.

Claims 7, 8 and 10 are amended to depend from Claim 16. These claims are also amended to exclude the recitation of certain diseases treatable or to be treated by the Claim 16 compound, as will be clear from inspection of the claims.

THE DETAILED ACTION

Reconsideration and withdrawal of the holding that the Information Disclosure Statements (IDSs) filed June 30, 2004 and September 3, 2004 have not been considered are requested.

Those two IDSs referred to copending applications. It is no longer required to submit copies of cited pending application. Please see the attached published final rule.

Reconsideration and withdrawal of the rejection of Claims 8 and 10 under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for treating diseases/disorders such as diabetes, osteoporosis, hypertension, atherosclerosis, polycystic ovary syndrome, etc., does not reasonably provide enablement for the prophylaxis, or prevention, of all the diseases/disorders listed in Claims 8 and 10.

The claims have been amended by deleting certain diseases.

Of the diseases itemized in the claims and not listed above, the following comments are made. (Reference to the Merck Manual are to the 16th Edition. Copies of pages 1039-1043, 1046, 1047, 1106-1113, 1118, 1119, 1888-1893 are enclosed).

Impaired glucose tolerance is diagnostic for diabetes and high glucose in plasma. Hypoglycemic agents are designed to be effective to treat just such a characteristic (Merck Manual, pages 1112 and 1119).

Insulin resistance syndrome would seem to be treatable as Applicants disclose because a hypoglycemic agent can stimulate insulin secretion. Merck Manual, page 1119. The attached Pub Med Abstract of an article entitled "Insulin Resistance and its Treatment by Thiazolidinediones", by Lebowitz, Recent Prog. Horm. Res., 2001; 56; 265-94, contains the following statements (underlining supplied):

Associated with insulin resistance, however, is a cluster of other metabolic abnormalities involving body fat distribution, lipid metabolism, thrombosis and fibrinolysis, blood pressure regulation, and endothelial cell function. This cluster of

abnormalities is referred to as the insulin resistance syndrome or the metabolic syndrome. It is casually related not only to the development of type 2 diabetes but also to cardiovascular disease.

and further:

Specifically, the thiazolidinediones improve insulin action and decrease insulin resistance. The exact mechanism by which these agents decrease insulin resistance is not clear but they do decrease the elevated free fatty acid levels present in insulin-resistant patients and they appear to change the body distribution of adipose tissue. Treatment of insulin-resistant type 2 diabetic patients with thiazolidinediones not only improves glycemic control and decreases insulin resistance, it also improves many of the abnormalities that are part of the insulin resistance syndrome.

The thiazolidinediones are a class of agents used to treat type 2 diabetic patients.

They are known oral type 2 glycemic agents, please see the previously submitted Remington text, page 1374. Therefore, it is reasonable to conclude that Applicants' disclosure is enabling.

Gestational diabetes is diabetes associated with gestation. Applicants disclose that it treatable. Note high glucose level is diagnostic for gestational diabetes (Merck Manual, pages 1112, 1888-1893).

Diabetic complications, by definition, are initiated by diabetes. Hence, treating the latter treats the former.

Hyperlipedemia (hyperlipoproteinemia) can be caused by diabetes and is associated with glucose intolerance, note type IV, pages 1039 and the chart page 1042, columns 1, 6 and 7 of the Merck Manual. Please see also the Lebowitz article.

A hypoglycemic agent is intended to treat hyperglycemia by definition (Merck Manual, page 1119).

The Arch Dermatol., 2000, 136(5) 609-16 citation of record teaches that Troglitazone, a hypoglycemic agent, is effective for psoriasis, i.e., one of the skin disorders relating to an

anomaly of differentiation of epidermic cells as previously noted, see also Merck Manual, page 2435 first two paragraphs for a discussion of psoriasis.

All the other recited treatments are acknowledged to be enabled.

The In re Wands factors were addressed in the previous response.

The rejection of Claims 2, 3, and 5 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is now moot in view of the deletion of those claims.

The rejection of Claims 1-8 and 10-12 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-10 of U.S. Patent No. 6,242,474 is now moot in view of the deletion of those claims.

Claim 13 was indicated to be allowable if rewritten in independent form including all of the limitations and any intervening claims. It is so rewritten as new Claim 16. All other claims depend directly or indirectly from Claim 16.

Favorable reconsideration of the here amended application is solicited.


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